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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,593	02/15/2002	Ellen M. Heath	GISM-P01-011	9392

7590 08/03/2005

Ropes & Gray
Suite 800 East
1301 K Street, NW
Washington, DC 20005

EXAMINER	
CHUNDURU, SURYAPRABHA	
ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 08/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

NEW CENTRAL FAX NUMBER

Effective July 15, 2005

On July 15, 2005, the Central FAX Number will change to **571-273-8300**. This new Central FAX Number is the result of relocating the Central FAX server to the Office's Alexandria, Virginia campus.

Most facsimile-transmitted patent application related correspondence is required to be sent to the Central FAX Number. To give customers time to adjust to the new Central FAX Number, faxes sent to the old number (703-872-9306) will be routed to the new number until September 15, 2005. After September 15, 2005, the old number will no longer be in service and **571-273-8300** will be the only facsimile number recognized for "centralized delivery".

CENTRALIZED DELIVERY POLICY: For patent related correspondence, hand carry deliveries must be made to the Customer Service Window (now located at the Randolph Building, 401 Dulany Street, Alexandria, VA 22314), and facsimile transmissions must be sent to the Central FAX number, unless an exception applies. For example, if the examiner has rejected claims in a regular U.S. patent application, and the reply to the examiner's Office action is desired to be transmitted by facsimile rather than mailed, the reply must be sent to the Central FAX Number.

Office Action Summary	Application No.	Applicant(s)	
	10/075,593	HEATH ET AL.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-17,19-28,30-49,51-59 and 61-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-17,19-28,30-49,51-59 and 61-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' response to the office action filed on May 24, 2005 has been entered.

2. Claims 1-7, 9-17, 19-28, 30-49, 51-59, 61-65 are pending.

Status of the Application

3. Applicants' response to the office action is fully considered and found not persuasive. All arguments have been fully considered and thoroughly reviewed, but are deemed not persuasive for the reasons that follow. This action is made FINAL.

4. The following are the rejections made in the previous office action:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

A. Claims 1-4, 9-16, 30-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Henco et al. (USPN. 5, 057,426).

With reference to the instant claims 1-2, and 24, Henco et al. teach a method for isolating DNA from a biological sample wherein Henco et al. teach that the method comprises (a) separating the biological material comprising DNA from remainder of the biological sample (see column 11, lines 53-59, column 12, lines 20-25); (b) contacting the separated biological material comprising DNA with a hypertonic high salt solution so as to form a suspension of said

biological material containing DNA (see column 10, lines 30-40, column 12, lines 26-32); (c) contacting the suspension with a cell lysis reagent to release DNA from non-DNA components (see column 11, lines 60-63); (d) physically separating DNA by centrifugation to yield isolated DNA (see column 11, lines 64-68, column 12, lines 1-15).

With reference to the instant claims 3-4, 9-16, 30-37, Henco et al. also teach that (i) the method comprises biological material comprising bacterial cells, viruses, vegetable and animal tissue cells (see column 5, lines 10-21); lysis reagent comprises sodium dodecyl sulfate an anionic detergent greater than 0.1% w/v (see column 11, lines 60-63); (ii) high salt solution comprises sodium salts (3M sodium acetate) (see column 11, lines 63-67). Thus the disclosure of Henco et al. meets the limitations in the instant claims.

B. Claims 1-3, 6-7, 9-10, 13-16, 19-21, 23-25, 27-28, 30-31, 34-37, 40-42, 44-46, 48-49, 51-52, 55-58, 61-63, 65 are rejected under 35 U.S.C. 102(b) as being anticipated by Miller et al. (Nucleic Acids Res., Vol. 16, No.3, 1988).

With reference to the instant claims 1-2, 24, 45, Miller et al. teach a method for isolating DNA from a biological sample comprising cells (whole blood) wherein Miller et al. disclose that the method comprises sequential steps:

(a) separating the biological material comprising DNA (white blood cells or buffy coats) from remainder of the biological sample (anticoagulated blood)(see page 1215, paragraph 2, lines 1-2);

(b) contacting the separated biological material comprising DNA with a hypertonic high salt solution (Nuclei lysis buffer containing 10mM Tris-HCl, 400 mM NaCl, and 2mM

Na_2EDTA, pH 8.2) so as to form a suspension of said biological material containing DNA (see page 1215, paragraph 2, lines 2-4);

(c) contacting the suspension with a cell lysis reagent (1mg protease K in 1% SDS and 2mM Na_2EDTA) to release DNA from non-DNA components (see page 1215, paragraph 2, lines 4-7);

(d) physically separating DNA by precipitation to yield isolated DNA (see page 1215, paragraph 2, line 7-19).

With regard to claims 3, 6, 25, 27, 46, 48, Miller et al. teach that the biological sample is from whole blood (anticoagulated blood) (see page 1215, paragraph 2, line 1-2);

With regard to the instant claims 7, 28, 49, Miller et al. teach that the non-DNA biological component comprises protein (see page 1215, paragraph 2, line 10);

With regard to claims 9-10, 30-31, 51-52, Miller et al. teach that the hypertonic solution comprises sodium salt in an effective amount to precipitate proteins out of lysate (see page 1215, paragraph 1, lines 6-10, paragraph 2);

With regard to claims 19-20, 40-41, 61-62, Miller et al. teach that physically separating the DNA from lysate comprises precipitating non-DNA biological components from lysate by centrifugation without adding any additional reagents (see page 1215, paragraph 2);

With regard to claim 21, 42, 63, Miller et al. also teach isolated DNA is contacted with wash solution an alcohol to precipitate isolated DNA (see page 1215, paragraph 2);

With regard to claim 23, 65, Miller et al. teach that the isolated DNA is treated with a hydration reagent (TE buffer) (see page 1215, paragraph 2);

With regard to claims 13-16, 34-37, 55-58, Miller et al. teach that the lysis reagent comprises anionic detergent , sodium dodecyl sulfate with a concentration greater than 0.1% w/v (see page 1215, paragraph 2, line 4-6).

Thus the disclosure of Miller et al. meets the limitations in the instant claims.

C. Claims 1-3, 5-6, 13-17, 25-27, 34-38, 46-48, 55-59 are rejected under 35 U.S.C. 102(e) as being anticipated by Tomita (US 2003/0082616 A1).

With reference to the instant claims 1-2, 24, 45, Tomita et al. teach a method for isolating DNA from a biological sample comprising cells (whole blood) wherein Tomita et al. disclose that the method comprises sequential steps:

(a) separating the biological material comprising DNA (separating whole blood) from remainder of the biological sample (from a subject)(see page 8, paragraph 0073, line 1, paragraph 0047);

(b) contacting the separated biological material comprising DNA (whole blood) with a hypertonic high salt solution (NaCl) so as to form a suspension of said biological material containing DNA (see page 8, paragraph 0073, lines 1-4);

(c) contacting the suspension with a cell lysis reagent to release DNA from non-DNA components (see page 8, paragraph 0075-0076);

(d) physically separating DNA by precipitation to yield isolated DNA (see page 8, paragraphs 0077-0081).

With regard to claims 3, 5-6, 25-27, 46-48, Tomita et al. teach that the biological sample is from whole blood, bone marrow, biopsy tissue (see page 5, paragraph 0047);

With regard to claims 13-16, 34-37, 55-58, Tomita et al. teach that the lysis reagent comprises anionic detergent , sodium dodecyl sulfate with a concentration greater than 0.1% w/v (see page 8, paragraph 0075);

With regard to claims 17, 38, 59, Tomita et al. teach that the lysis buffer comprises RNase (see page 8, paragraph 0075).

Thus the disclosure of Tomita et al. meets the limitations in the instant claims.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 22, 43, and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (Nucleic Acids Res., Vol. 16, No.3, 1988) in view of Gray et al. (USPN. 5, 777, 098).

Miller et al. teach a method for isolating DNA from a biological sample comprising cells (whole blood) wherein Miller et al. disclose that the method comprises sequential steps:

(a) separating the biological material comprising DNA (white blood cells or buffy coats) from remainder of the biological sample (anticoagulated blood)(see page 1215, paragraph 2, lines 1-2);

(b) contacting the separated biological material comprising DNA with a hypertonic high salt solution (Nuclei lysis buffer containing 10mM Tris-HCl, 400 mM NaCl, and 2mM Na_2EDTA, pH 8.2) so as to form a suspension of said biological material containing DNA (see page 1215, paragraph 2, lines 2-4);

(c) contacting the suspension with a cell lysis reagent (1mg protease K in 1% SDS and 2mM Na_2EDTA) to release DNA from non-DNA components (see page 1215, paragraph 2, lines 4-7);

(d) physically separating DNA by precipitation to yield isolated DNA (see page 1215, paragraph 2, line 7-19).

Miller et al. also teach that the biological sample is from whole blood (anticoagulated blood) (see page 1215, paragraph 2, line 1-2); the non-DNA biological component comprises protein (see page 1215, paragraph 2, line 10); the hypertonic solution comprises sodium salt in an effective amount to precipitate proteins out of lysate (see page 1215, paragraph 1, lines 6-10, paragraph 2); the physically separating the DNA from lysate comprises precipitating non-DNA biological components from lysate by centrifugation without adding any additional reagents (see page 1215, paragraph 2); isolated DNA is contacted with an alcohol to precipitate isolated DNA

(see page 1215, paragraph 2); the isolated DNA is treated with a hydration reagent (TE buffer) (see page 1215, paragraph 2).

However, Miller et al. did not specifically teach contacting isolated DNA with a wash solution.

Gray et al. Gray et al. teach a method for DNA purification wherein Gray et al. teach that the method comprises (a) separating the biological material comprising DNA from remainder of the biological sample which includes contacting whole blood with a red blood lysis solution and separating white blood cells comprising DNA (see column 2, lines17-25, column 3, lines 1-21, column 7, lines 1-12); (b) contacting the separated biological material (white blood cells) comprising DNA with a hypertonic high salt solution so as to form a suspension of said biological material containing DNA (see column 4, lines 48-58); (c) contacting the suspension with a cell lysis reagent to release DNA from non-DNA components (see column 4, lines 34-36); (d) physically separating DNA by centrifugation to yield isolated DNA (see column 5, lines 1-11). Gray et al. also teach that physically separating the DNA from the lysate comprises precipitating DNA with an alcohol, followed by a wash solution (see column 5, lines 1-11).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to combine a method of isolating DNA from a biological sample as taught by Miller et al. with an additional wash solution step as taught by Gray et al. to achieve expected advantage of developing a enhanced method of extracting purified DNA because Gray et al. suggests that "the repeated wash steps would yield only the DNA without any contaminating reagents (see col. 5, line 3-11). It is further noted that selection of parameters such as additional wash solution step for routine optimization are explicitly recognized in Gray et

al. As noted in *In re Aller*, 105 USPQ 233 at 235, More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. Routine optimization is not considered inventive and no evidence has been presented that the wash solution step performed was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art. An ordinary practitioner would have been motivated to combine the method of Miller et al. with the limitations such as additional the wash solution, as taught by Gray et al. for the purpose of reducing contaminating reagents, and to improve the quality and yield of the DNA.

Response to arguments:

4. With regard to the rejection under 35 USC 102(b) as anticipated by Henco et al., Applicants' are fully reviewed and found unpersuasive. Applicants argue that Henco does not teach hypertonic solution and brings to the Examiners' attention, the instant specification defining hypertonic solution comprising a salt concentration greater than 1.0M and also argue that Henco et al. teach a solution comprising a salt concentration ranging from 0.3 to 0.7M. Applicants' arguments are fully considered and found unpersuasive. As noted in the MPEP, Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In the instant situation, the hypertonic solution comprising a salt concentration grater than 1-0M is not present in the claims and the term hypertonic is broader in scope and could include any range of salt solution, thus the salt concentration around 0.7M as taught by Henco et al. meets the limitation in the instant claims. Applicants' further argue that Henco et al. does not teach lysing

the biological material after addition of hypertonic solution. Applicants' arguments are fully considered and found unpersuasive. Henco et al. does teach contacting biological material with a hypertonic solution as cited in Col. 10, line 30-40, and col. 12, line 19-32, and followed by adding a lysis solution (see col. 12, line 33-40, line 47-68, indicating the lysis buffer comprising EDTA and Triton X). Thus Henco et al. teach all the limitations in the instant claims and the rejection is maintained herein.

5. With regard to the rejection under 35 USC 102(b) as anticipated by Miller et al. Applicants arguments are fully considered and found unpersuasive. Applicants argue that Miller et al. does not teach addition of hypertonic solution before lysing the biological material and does not anticipate the instant claims and argue that Applicants argue that Miller et al teach addition of 6M Nacl after adding the lysis solution. Applicants' arguments are fully considered and found unpersuasive. As discussed above the instant claims do not recite hypertonic solution as solution comprising a salt concentration greater than 1.0 M and the specification cannot be read into the claims. The instant claims are broader in scope in reciting broadly "a hypertonic solution", which do not exclude any salt solution comprising a salt concentration effective of forming a suspension of said biological material. Miller et al. does teach adding a hypertonic solution (salt concentration of 0.4 M) before adding a lysis solution. Since the claims are in open "comprising" format any additional steps are included and thus addition of 6M Nacl is considered as an additional step and thus the rejection is maintained herein.

6. With regard to the rejection under 35 USC 102(e) as anticipated by Tomita et al. Applicants arguments are fully considered and found unpersuasive. Applicants argue that Tomita et al. teach addition of a salt solution comprising less that 1.0M concentration and does not teach a

hypertonic solution comprising a salt concentration greater than 1.0M. Applicants' arguments are fully considered and found unpersuasive. As discussed above the instant claims do not recite hypertonic solution as solution comprising a salt concentration greater than 1.0 M and the specification cannot be read into the claims. The instant claims are broader in scope in reciting broadly "a hypertonic solution", which do not exclude any salt solution comprising a salt concentration effective of forming a suspension of said biological material. Miller et al. does teach adding a hypertonic solution (0.5% NaCl) before adding a lysis solution and thus the rejection is maintained herein.

6. With regard to the rejection under 35 USC 103(a) as being obvious over Miller et al. in view of Gary et al. Applicants' arguments are fully considered and found not persuasive. Applicants argue that Miller et al. does not teach the hypertonic solution and Miller et al. in view of Gary et al. does not make the instant claims obvious. Applicants' arguments are fully considered and found unpersuasive and as discussed above Miller et al. does teach hypertonic solution and the combination of Miller et al. and Gary make the instant claims obvious as discussed in the rejection above. Therefore the rejection is maintained herein.

Conclusion

No claims are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782 . The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Suryaprabha Chunduru
July 26, 2005

JEFFREY FREDMAN
PRIMARY EXAMINER
7/26/05

Notice of References Cited	Application/Control No. 10/075,593	Applicant(s)/Patent Under Reexamination HEATH ET AL.	
	Examiner Suryaprabha Chunduru	Art Unit 1637	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-5,057,426	10-1991	Henco et al.	435/270
*	B	US-2003/0082616 A1	05-2003	Tomita et al.	435/6
*	C	US-5,777,098	07-1998	Gray et al.	536/25.41
	D	US-			
	E	US-			
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	G	US-			
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	I	US-			
	J	US-			
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	L	US-			
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FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
*	U	Miller et al. A simple salting out procedure for extracting DNA from human nucleated cells. Nucleic Acids Res., Vol. 16, No. 3, page 1215, 1988.
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.